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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, and TAKEDA PHARMACEUTICALS U.S.A., INC.	)
Plaintiffs,	) C.A. No. 2:20-cv-8966-SRC-CLW
v.	)
NORWICH PHARMACEUTICALS, INC. Defendant.	)

TAKEDA'S REPLY CLAIM CONSTRUCTION BRIEF

TABLE OF AUTHORITIES

Cases

Statutes

Takeda submits this Reply Brief, as well as the declarations of Dr. Chyall ("Chyall Reply") and Mr. Roper with exhibits 80-88, in further support of Takeda's construction of the "mesylate" terms. The Court authorized (ECF No. 126) this Reply Brief to allow Takeda to respond to new arguments and a new reference—U.S. Patent Pub. No. 2018/0134658 A1 ("the '658 publication")—submitted with Norwich's responsive brief, which were not disclosed as required by Local Patent Rules 4.2 and 4.3 and the Court's Pretrial Scheduling Order. (*E.g.*, ECF Nos. 43, 77, 114 (Exhibit 79 at 1114)).

Norwich's reliance on the '658 publication to advance its construction of the "mesylate" terms is misplaced for several reasons. First, the '658 publication is not prior art, is irrelevant to claim construction, and constitutes inadmissible hearsay. Second, the '658 publication does not support Norwich's position. Third, no reference in the prior art discloses hemimesylate. Thus, the Court should reject Norwich's new arguments on the merits.

The '658 publication is **not** prior art. Nonetheless, relying solely on the '658 publication, Norwich misleadingly alleges that "hemi-mesylate salts are known in the art." (ECF No. 111 at 15; *see also id.* at 16 ("The art's disclosure of a hemi-mesylate salt . . . .")). But, the face of the '658 publication states that it was published on May 17, 2018, and its earliest priority document was filed on July 24, 2015. Not only did the '658 publication publish after the priority and issue dates of the Patents-in-Suit, it published after the Federal Circuit affirmed this Court's prior award of summary judgment of no invalidity of those patents. *Shire, LLC v. Amneal Pharm., LLC*, 802 F. 3d 1301, 1311 (Fed. Cir. Sept. 24, 2015). Even Dr. Hollingsworth admitted that "the '658 publication published after the priority date of the Patents-in-Suit." (ECF 111-2 at ¶ 16). Because the '658 publication is not prior art, it neither shows what a POSA would have known at the time

of the invention nor informs how a POSA would have understood the "mesylate" terms. In that regard, the '658 publication is "irrelevant . . . The court may only consider how a patent's claims would have been understood at the time of its effective filing date." *See, e.g.*, *Am. Med. Sys. v. Biolitec, Inc.*, 569 F. Supp. 2d 313, 322 n.2 (D. Mass. 2008). Moreover, because Norwich offers the '658 publication to prove the truth of the matter purportedly asserted therein (i.e., that hemimesylate salts exist), the '658 publication is inadmissible hearsay. *See* FED. R. EVID. 801(c). While it is true that "[s]tatements in a reference offered for their effect on one of ordinary skill in the art are not hearsay," where, as here, the statements were not in existence as of the relevant date, and thus cannot have had an effect on the POSA, they are hearsay. *Cf. Neev v. Abbott Med. Optics, Inc.*, No. 09-146 (RBK), 2012 U.S. Dist. LEXIS 42024, at *38-39 (D. Del. Mar. 26, 2012). Accordingly, the Court should give the '658 publication **no consideration**.

Even if the Court considers the '658 publication—which it should not—the '658 publication fails to support Norwich's position. First, the '658 publication does not illustrate salts with neutral molecules and hydrogen bonding. (Chyall Reply ¶¶ 205, 218). The salts drawn in the '658 publication show ionic bonds, not neutral molecules. (Chyall Reply ¶¶ 205-206, 218; '658 Publication ¶¶ [0262], [0265], [0267], [0270], [0272]-[0274]). And, Norwich has not pointed to any reference disclosing a salt, let alone a mesylate salt, with neutral molecules or hydrogen bonds. In that regard, the '658 publication supports Takeda's construction of "mesylate." Second, the '658 publication uses "hemimesylate" in a nominal or short-hand fashion rather than a scientifically precise manner. For example, "free base" is also listed under the salt column of Table 2. (Chyall Reply ¶ 192). But, free base clearly is **not** a salt. (Chyall Reply ¶ 192). Likewise, "lactate" is listed under the salt column of Table 2, but the '658 publication recognizes that "lactate [] did **not** form a salt . . . ." (Chyall ¶¶ 197-198; '658 Publication ¶ [0281]). Similarly, the '658

publication appears to be using "hemimesylate" as a short-hand for a mixture of free base and monomesylate salt. (Chyall Reply ¶¶ 193, 195-96). Third, when the authors of the '658 publication sought and obtained patent claims covering the mesylate salt, they were directed only to monomesylate. (Ex. 80 (claim 6 of '035 Patent); Chyall Reply ¶ 213). Likewise, when the authors published their research in a peer-reviewed journal, they never used the term "hemimesylate." (Ex. 87; Chyall Reply ¶ 219). For these reasons, the '658 publication does not advance Norwich's position.

Finally, the prior art reveals **zero** references disclosing hemimesylate salts. Norwich argued that Dr. Chyall should have done "literature searching" for hemimesylates. (Def. Resp. Br. 15, ECF No. 111). While at deposition Dr. Chyall explained that no such search was needed (ECF No. 112-2 at 36:2-8), he has since performed a search. The results corroborate his opinion that hemimesylate does not exist. For example, Dr. Chyall searched SciFinder-n—a highly regarded program for conducting chemical literature searches—and found **zero** results. (Chyall Reply ¶ 177; Ex. 84). Dr. Chyall searched all FDA-approved products and found **zero** results. (Chyall Reply ¶ 175; Ex. 85). Dr. Chyall then searched the USPTO's records and found only one patent family—the '658 publication's family—which is **not** prior art. (Chyall Reply ¶ 80; Ex. 86). These searches (SciFinder-n, Drugs@FDA, and USPTO) did not have temporal limitations. While Norwich states that hemimesylates were "known in the art," a thorough search reveals the opposite.

In sum, the '658 publication should be given no weight because (i) it is not prior art, (ii) it is irrelevant and hearsay, (iii) it does not support Norwich's position, and (iv) a proper search reveals that there are zero prior art references disclosing hemimesylate salts. (*See* Chyall Reply ¶¶ 174-219). Regardless, the '658 publication supports Takeda's—not Norwich's—construction of the "mesylate" terms. Thus, the Court should adopt Takeda's construction of "mesylate."

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of (i) Takeda's Reply Claim Construction Brief, (ii) Declaration of Dr. Leonard J. Chyall, Ph.D. in Support of Takeda's Reply Claim Construction Brief, and (iii) Declaration of Andrew S. Roper, Esq. in Support of Takeda's Reply Claim Construction Brief (including Exhibits 80-88) were caused to be served on all counsel of record by email and ECF on November 2, 2021.

/s/ Christine A. Gaddis
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